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K 955612

## 510(k) Summary

RE: K955612, 510(k) Spectrum Epilaser® Normal Mode Ruby Laser

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Submitted by: Spectrum Medical Technologies, Inc.  
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Proprietary Name: Epilaser®

Common Name: Dermatology Laser System

Predicate Devices: The Epilaser® was compared to pre-enactment normal mode ruby laser devices of substantially equivalent physical characteristics and indications for use and to post enactment devices with substantially equivalent mechanisms of action and indications for use. Data from in vitro, in vivo and clinical results found in the open literature were also provided

Device Description: The Epilaser® is a normal mode ruby laser operating at 694.3 nanometers with fluence levels from 10-40 J/cm<sup>2</sup>, a pulse duration from 200 µsec to 3 msec and a spot size of 5-12 mm. The delivery system includes an articulating arm and cooled contact handpiece.

Intended Uses: The Spectrum Epilaser® has several indications for use based on the selective absorption of natural chromophores, particularly melanin and tattoos. The Ruby laser wavelength of 694.3 nanometers and the pulse duration of the normal mode system are well absorbed by these pigments. Indications for use include the treatment of benign epidermal pigmented lesions such as lentigines and café au lait and tattoos (blue and black)

The Epilaser® was demonstrated to be substantially equivalent to the predicate devices on the basis of similar mechanisms of action and indications for use.